



**BlueCross BlueShield  
Association**

An Association of  
Independent Blue Cross  
and Blue Shield Plans

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June 1, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
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By Hand  
By E-Mail

To Whom It May Concern:

I am writing on behalf of the Blue Cross and Blue Shield Association to submit a written notice of participation for the June 28<sup>th</sup> and 29<sup>th</sup> public hearing announced in the April 27, 2000, Federal Register (65 FR 24704-24706), on the topic of "Over-the-Counter Drug Products". The Blue Cross and Blue Shield Association represents 48 independent Blue Cross and Blue Shield Plans that provide health coverage for 75 million Americans.

Dr. Allan Korn, Senior Vice President Clinical Affairs and Chief Medical Officer, of the Blue Cross and Blue Shield Association would like 10 minutes on June 29<sup>th</sup>, the second day of the hearing, to speak on the following questions raised in the April 27<sup>th</sup> notice:

- In the context of the present environment, what criteria should FDA consider in rendering decisions on OTC availability of drug products?
- Under what circumstances should FDA actively propose OTC marketing for a drug in the absence of support from the drug sponsor? (BCBSA also is interested in commenting on the role of interested third parties in this process.)
- Should FDA be more active in initiating switches of prescription products to OTC use?

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Thank you very much for your consideration. I look forward to hearing from you as to the time on June 29<sup>th</sup> that Dr. Korn will present his oral comments. If you have any questions about the nature of Dr. Korn's presentation, please call Julie Miller at 202.626.8625.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary Nell Lehnhard". The signature is fluid and cursive, with the first name "Mary" being the most prominent.

Mary Nell Lehnhard  
Senior Vice President  
Office of Policy and Representation